

REMARKS

The present document is submitted in response to the final Office Action dated May 13, 2010 (“the Office Action”).

At the Examiner’s suggestion, Applicant has amended claim 1, sub-part (i), to remove alleged new matter. Support for item (1) added to sub-part (i) can be found in the Specification at page 3, lines 6-13. Applicant has also amended claim 1 by adding an evaluating step. Support for “evaluating … a therapeutic effect of [a] composition on the skin, mucosa, injured normal tissue, or epithelium of [a] subject” appears in the Specification at page 23, lines 9-10 (evaluating skin); page 22, lines 14-15 (evaluating injured normal tissue); page 23, line 29 (evaluating epithelium); page 32, Example 13 (evaluating mucosa). These passages disclose animal studies, which examined a histone hyperacetylating agent’s therapeutic effect on skin, injured normal tissue, epithelium, and mucosa. In view of this disclosure, one skilled in the art would clearly recognize that skin, injured normal tissue, epithelium, and mucosa must be evaluated to ascertain the therapeutic effect. That is, the passages support the proposed amendment.<sup>1</sup> Finally, Applicant has amended withdrawn claims 8 and 10 to correct typographical errors. No new matter has been introduced.

Claims 1-4 and 6-21 are pending. Among them, claims 2-4, 6-10, 12, 13, and 18-21 have been withdrawn from consideration and claims 1, 11, and 14-17 are under examination. Applicant has filed herewith a Request for Continued Examination and requests that the above-mentioned amendment be entered and this application be reconsidered in view of the following remarks.

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<sup>1</sup> The exact words of the proposed amendment do not have to be set forth verbatim in the specification. In *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989), the Federal Circuit, in reversing a Board’s 35 U.S.C. § 112, first paragraph rejection, held that there was adequate written description support for applicant’s claim limitation, despite the fact that it was not set forth “*in haec verba*” (i.e., “in these words” or “verbatim”) in the specification.

Also, according to MPEP 2163.02, when determining whether a specification is in compliance with the written description requirement, “the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art, as of the filing date sought, applicant was in possession of the invention as now claimed… the subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.”

35 U.S.C. § 112 Rejections

Claims 1, 11, and 14-17 were rejected for containing new matter, which, according to the Office Action, broadens the original claim scope. See page 2, line 21 to page 4, line 10. In the sole interest of moving this case forward, Applicant has amended independent claim 1 in the manner suggested by the Examiner to remove the alleged new matter.

The Examiner further rejected the claims for containing new matter, stating that “claim 1, part (iii) … is only associated with histone ‘deacetylase inhibitor’ effects and not with the generic histone ‘hyperacetylating agent.’” See the Office Action, pages 4-5, carryover paragraph.

Applicant respectfully traverses. Claim 1, part (iii) relates to use of a histone hyperacetylating agent for “promoting radiation-induced wound healing in mucositis and dermatitis.” Applicant would like to point out that this use is clearly supported by original claim 2. Specifically, original claim 2 recites

2. The method as claimed in claim 1, wherein the increased therapeutic gain is simultaneously enhancing tumor radiosensitization or sensitizing tumors to chemotherapy, increasing tumor growth inhibition, promoting wound healing in mucositis and dermatitis, preventing/reducing severity of plantar-palmar syndrome, decreasing tissue fibrosis, protecting normal tissue from cell death, preventing xerostomia, and suppressing tumorigenesis [emphases added].

Original claim 1, from which original claim 2 depends, recites a step “administering a composition of a histone hyperacetylating agent and a pharmaceutically acceptable carrier or a pharmaceutically acceptable salt thereof to a subject in need.” It follows that claim 2 covers use of a histone hyperacetylating agent for “promoting radiation-induced wound healing in mucositis and dermatitis,” i.e., part (iii) of present claim 1. In other words, part (iii) of present claim 1 is supported by original claims 1 and 2. As the Examiner is aware of, “[t]he claims as filed in the original specification are part of the disclosure.” See MPEP 2163.06 III. Thus, Applicant submits that claim 1, part (iii) contains no new matter.

In view of the above amendments and remarks, Applicant respectfully requests that the rejections be withdrawn.

35 U.S.C. § 103 Rejections

Claims 1, 11, and 14-16 were rejected for obviousness over US Patent No. 5,877,213 to Samid (“Samid”). See the Office Action, page 5, lines 13-14.

Applicant has amended independent claim 1 and will discuss this claim first. Claim 1 as amended, covers a method for treating skin-related side effects that were induced by chemotherapy or radiotherapy by administering a histone hyperacetylating agent to a subject in need. The claimed method requires, among others, evaluating the subject for a therapeutic effect of the composition on the skin, mucosa, injured normal tissue, or epithelium of the subject.

In contrast, Samid describes compositions and methods for treating anemia, cancer, AIDS, or severe  $\beta$ -chain hemoglobinopathies by administering a therapeutically effective amount of phenylacetate and its derivatives, e.g., phenylbutyrate (a histone hyperacetylating agent). See Samid, Abstract. It does not teach or suggest treating any skin-related side effects in a subject, much less a step of evaluating the subject for a therapeutic effect of the composition on the skin, mucosa, injured normal tissue, or epithelium of the subject, as required in amended claim 1. Thus, in view of the above amendments and remarks, Applicant submits that claim 1 is not obvious over Samid. Nor are claims 11 and 14-17, all of which depend from claim 1.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any

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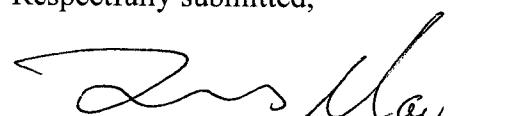
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claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 55701-004002.

Respectfully submitted,

Date: 7-1-2010

  
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